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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,778	09/21/2005	Oliver German Perez Martin	LEXSA.P32	2870

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/536,778	PEREZ MARTIN ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Preliminary Amendment*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26May2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Preliminary Amendment is acknowledged. Claims 1-50 have been amended. New claims 51-55 have been added.

2. Claims 1-55 are pending and under consideration.

Priority Statement

3. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. There is no priority statement at the beginning of the specification claiming benefit of the prior documents.

Specification

4. The disclosure is objected to because of the following informalities:

Page 2, line 19, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 5, line 4, why is "teicoic" underlined? Line 6 and 12, "*tiphy*" should be "*typhl*"; line 12, "*Meningitidis*" should be "*meningitidis*"; line 17, what is "histiocytary"?; line 23, "Tiphy" should be "*typhl*".

Page 6, line 7, "solutions" should be "solution"; line 32, "amastygotes or promastygotes" should be "amastigotes or promastigotes"; line 36, "macrophagyc" should be "macrophagic".

Page 7, line 1, why is "alergenic" underlined? It is also misspelled; line 36, should "tinted" actually be "stained"?

Page 8, lines 10 and 21, what is "seric", because it is not a word found in English dictionaries.

Page 9, lines 3 and 14, what is "seric", because it is not a word found in English dictionaries.

Page 10, line 34, should "reveral" actually be "reversal"?

Page 11, lines 19, and 32, what is the actual concentration "of µg/ml"?

Page 12, lines 13 and 30, were the cell actually incubated with 200 liters or actually "200 ml"?; lines 14, 25, 31, was the medium DMEN, or actually D-MEM?; line 14, "concentrastion" should be "concentration".

Page 13, lines 15, 18, "amastygotes" should be "amastigotes"; line 25, "polyacrilamyde gels tinted" should be "polyacrylamide gels stained"; lines 28, 29, "promastygotes" should be "promastigotes"; line 30, was the medium DMEN, or actually D-MEM?

Page 14, line 8, "tinted" should be "stained"; lines 32, 33, "*tiphy*" should be "*typhl*".

Page 15, line 1, what is meant by "positivizes"?

Page 17, line 1, "them natural or recombining" should be "they natural or recombinant"; line 13, what is meant by "cold chain"?; line 23, "them" should be "they"; line 34, "cytokinins" should be "cytokines".

Page 18, line 4, "immonogenicity" should be "immunogenicity"; line 19, "acrylamyde" should be "acrylamide"; line 36, "intra- intra" should be "intra-".

Page 19, line 32, "amastygotes" should be "amastigotes", "*Leishmanais*" should be "*Leishmania*"; line 37, "*tiphy*" should be "*typhl*".

Page 20, there are no Brief Descriptions of Figures 25-29.

Appropriate correction is required.

Drawings

5. Figures 2-29 are objected to because they are not in English. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising cochlear structures for production of antibodies or for treating leishmaniasis, does not reasonably provide enablement for the extremely broad scope of the instant claims, i.e., a vaccine composition containing proteolipidic cochlear structures obtained from vesicles found in the outer membranes of any/all live microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a vaccine composition comprising proteolipidic cochlear structures obtained from vesicles found in the outer membranes of live microorganisms.

The state of the prior art for vaccine compositions varies, depending on the type of microorganism involved. Thus, there is a lack of predictability in the art that *a priori* any composition comprising proteolipidic cochlear structures as claimed would result in preventing disease due to the microorganism, because there is a lack of predictability that a composition of

outer membranes is sufficient for a vaccine. For example, see Wang et al, concerning tuberculosis vaccines, and Gallo, concerning HIV vaccines.

The amount of direction or guidance present only shows that claimed structures from *L. major* reduce the number of indurations in mice, or that various *in vitro* tests are altered. The specification does not provide sufficient support for the extremely broad scope of the instant claims, i.e., a vaccine composition comprising proteolipidic cochlear structures obtained from vesicles found in any/all live microorganisms.

Thus, the scope of the instant claims constitutes merely an invitation to experiment without a reasonable expectation of success.

8. Claims 2-4, 27-29, 37-39, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what are the metes and bounds of the phrase "associated to".

9. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by a group consisting "in" the listed materials.

10. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear an organism "comprises" the listed microorganisms.

Claim Objections

11. Claims 7-9, 22-24, 32-34, and 42-44 are objected to because of the following informalities: all names of bacteria should be in italics. Appropriate correction is required.

Conclusion

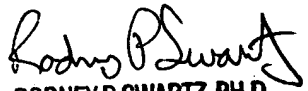
12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert M. Navarro, can be reached on (571)272-0861.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645